CONFIDENTIAL

K083295

510 (K) SUMMARY

MAR 16 2009

Prepared:	November 6, 2008
Submitter:	Serim Research Corporation
Address	P.O. Box 4002 Elkhart IN 46514
Phone: **Fax:**	574-264-3440 574-266-6222
Contact:	Patricia A. Rupchock Director of Regulatory Affairs
Device Trade Name:	Serim® DISINTEK™ GTA 2.1%
Common or Usual Name:	Indicator for CIDEXPLUS glutaraldehyde disinfectant solutions.
Device Classification Name:	Physical/Chemical Sterilization Process Indicator
Product Code:	JOJ
Class:	II
Regulation Number:	21CFR 880.2800
Substantial Equivalence:	The Serim® DISINTEK™ GTA 2.1% is substantially equivalent to CIDEXPLUS Solution test strips ; K981054
Device Description:	The device is a qualitative, single use, reagent test strip made up of a 0.40-inch square reagent pad that has been chemically treated to detect glutaraldehyde in CIDEXPLUS 28 Day solutions. The pad is affixed to one end of a 3.25 inch by 0.40-inch white opaque polystyrene strip.
Intended Use:	The Serim® Disintek GTA 2.1% Test Strip is a chemical indicator for use in determining whether the concentration of *glutaraldehyde* the active ingredient in CIDEXPLUS 28 Day Solution, is above or below the minimum effective concentration (MEC) established for CIDEXPLUS 28 Day Solution

Technological Characteristics: The Serim® Disintek GTA 2.1% Test Strips contain three reacting chemicals, and a background dye. The visual response given by the indicator pad of the test strip is based on the following chemical reactions.
Glutaraldehyde reacts with sodium sulfite to form a colorless addition product and a base. The base then reacts with a pH indicator producing a purple color. The indicator pad also contains sodium bisulfite, which reacts with both glutaraldehyde and with the base. When glutaraldehyde concentration is above the 2.1% level (MEC), enough base is produced to result in an irreversible and distinct color change of the indicator pad. Testing of freshly activated Cidex® Plus solutions always results in a solid purple color on the indicator pad. When the glutaraldehyde concentration is at or approaching the MEC level, the base is neutralized by the sodium bisulfite and the indicator pad will display a distinctly blotched yellow and purple appearance. The test pad size of 0.4" x 0.4" and a color block showing a representative color change for the MEC level allows for easy interpretation of the change in color. As the glutaraldehyde concentration approaches 1.5%, the indicator pad will appear mostly yellow. The device will reliably indicate if the glutaraldehyde concentration is above or below the MEC level of 2.1% in CIDEXPLUS 28 Day solutions.

Performance: The performance of the Serim Disintek GTA 2.1% Test Strips was evaluated in split samples blind studies and compared to test results obtained with CIDEXPLUS Solution Test Strips. The performance of the Serim Disintek GTA 2.1% Test Strips is substantially equivalent to the predicate device, CIDEXPLUS Solution Test Strips.

Conclusion: The Serim Disintek GTA 2.1% Test Strips have the same intended use as the predicate device. Both test strips measure the potency of GTA in CIDEXPLUS 28 Day Solution, above or below the Minimum Effective Concentration of 2.1%. The Serim Disintek GTA 2.1% Test Strips do not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 6 2009

Ms. Patricia Rupchock
Director of Regulatory Affairs
Serim Research Corporation
3506 Reedy Drive
Elkhart, Indiana 46514

Re: K083295
Trade/Device Name: Serim® DISINTEK™ GTA 2.1%
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: February 23, 2009
Received: February 26, 2009

Dear Ms. Rupchock:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

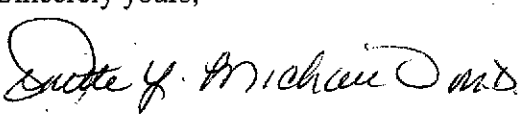
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K

Device Name: Serim® DISINTEK™ GTA 2.1%

Indications For Use: The Serim® Disintek GTA 2.1% Test Strip is a chemical indicator for use in determining whether the concentration of *glutaraldehyde*, the active ingredient in CIDEXPLUS 28 Day Solution, is above or below the minimum effective concentration (MEC) established for CIDEXPLUS 28 Day Solution.

Prescription Use _____ AND / OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Shirley A Murphy MD
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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